PLASMA-LYTE 56 - sodium chloride, potassium acetate and magnesium acetate tetrahydrate injection
Baxter Healthcare Corporation

DESCRIPTION

PLASMA-LYTE 56 Injection (Multiple Electrolytes Injection, Type 1, USP) is a sterile, nonpyrogenic, hypotonic solution in a single dose container for intravenous administration. Each 100 mL contains 234 mg of Sodium Chloride, USP (NaCl); 128 mg of Potassium Acetate, USP ($C_2H_3KO_2$); and 32 mg of Magnesium Acetate Tetrahydrate ($Mg(C_2H_3O_2)_2 \cdot 4H_2O$). It contains no antimicrobial agents. The pH is adjusted with hydrochloric acid. The pH is 5.5 (4.0 to 8.0).

PLASMA-LYTE 56 Injection (Multiple Electrolytes Injection, Type 1, USP) administered intravenously has value as a source of water and electrolytes. One liter has an ionic concentration of 40 mEq sodium, 13 mEq potassium, 3 mEq magnesium, 40 mEq chloride, and 16 mEq acetate. The osmolarity is 111 mOsmol/L (calc). Normal physiologic osmolarity range is approximately 280 to 310 mOsmol/L. Administration of substantially hypertonic solutions may cause vein damage.

The VIAFLEX plastic container is fabricated from a specially formulated polyvinyl chloride (PL 146 Plastic). The amount of water that can permeate from inside the container into the overwrap is insufficient to affect the solution significantly. Solutions in contact with the plastic container can leach out certain of its chemical components in very small amounts within the expiration period, e.g., di-2-ethylhexyl phthalate (DEHP), up to 5 parts per million. However, the safety of the plastic has been confirmed in tests in animals according to USP biological tests for plastic containers as well as by tissue culture toxicity studies.

CLINICAL PHARMACOLOGY

PLASMA-LYTE 56 Injection (Multiple Electrolytes Injection, Type 1, USP) has value as a source of water and electrolytes. It is capable of inducing diuresis depending on the clinical condition of the patient.

PLASMA-LYTE 56 Injection (Multiple Electrolytes Injection, Type 1, USP) produces a metabolic alkalinizing effect. Acetate ions are metabolized ultimately to carbon dioxide and water, which requires the consumption of hydrogen cations.

INDICATIONS AND USAGE

PLASMA-LYTE 56 Injection (Multiple Electrolytes Injection, Type 1, USP) is indicated as a source of water and electrolytes or as an alkalinizing agent.

CONTRAINDICATIONS

None known

WARNINGS

PLASMA-LYTE 56 Injection (Multiple Electrolytes Injection, Type 1, USP) should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency and in clinical states in which there exists edema with sodium retention.

PLASMA-LYTE 56 Injection (Multiple Electrolytes Injection, Type 1, USP) should be used with great care, if at all, in patients with hyperkalemia, severe renal failure and in conditions in which potassium retention is present.

PLASMA-LYTE 56 Injection (Multiple Electrolytes Injection, Type 1, USP) should be used with great care in patients with metabolic or respiratory alkalosis. The administration of acetate ions should be done with great care in those conditions in which there is an increased level or an impaired utilization of these ions, such as severe hepatic insufficiency.

PLASMA-LYTE 56 Injection (Multiple Electrolytes Injection, Type 1, USP) should not be administered simultaneously with blood through the same administration set because of the possibility of hemolysis.

The intravenous administration of PLASMA-LYTE 56 Injection (Multiple Electrolytes Injection, Type 1, USP) can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injection. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injection.

In patients with diminished renal function, administration of PLASMA-LYTE 56 Injection (Multiple Electrolytes Injection, Type 1, USP) may result in sodium or potassium retention.

PRECAUTIONS

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

PLASMA-LYTE 56 Injection (Multiple Electrolytes Injection, Type 1, USP) should be used with caution. Excess administration may result in metabolic alkalosis.

Caution must be exercised in the administration of PLASMA-LYTE 56 Injection (Multiple Electrolytes Injection, Type 1, USP) to patients receiving corticosteroids or corticotropin.

Pregnancy

Teratogenic Effects

Pregnancy Category C
Animal reproduction studies have not been conducted with PLASMA-LYTE 56 Injection (Multiple Electrolytes Injection, Type 1, USP). It is also not known whether PLASMA-LYTE 56 Injection (Multiple Electrolytes Injection, Type 1, USP) can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. PLASMA-LYTE 56 Injection (Multiple Electrolytes Injection, Type 1, USP) should be given to a pregnant woman only if clearly needed.

Pediatric Use
Safety and effectiveness of PLASMA-LYTE 56 Injection (Multiple Electrolytes Injection, Type 1, USP) in pediatric patients have not been established by adequate and well controlled trials, however, the use of electrolyte solutions in the pediatric population is referenced in the medical literature. The warnings, precautions and adverse reactions identified in the label copy should be observed in the pediatric population.

Geriatric Use
Clinical studies of PLASMA-LYTE 56 Injection (Multiple Electrolytes Injection, Type 1, USP) did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or drug therapy.
Do not administer unless solution is clear and seal is intact.

ADVERSE REACTIONS
Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.
If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.

DOSAGE AND ADMINISTRATION
As directed by a physician. Dosage is dependent upon the age, weight and clinical condition of the patient as well as laboratory determinations.
Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.
All injections in VIAFLEX plastic containers are intended for intravenous administration using sterile equipment.
Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

HOW SUPPLIED
PLASMA-LYTE 56 Injection (Multiple Electrolytes Injection, Type 1, USP) in VIAFLEX plastic containers is available as shown below:

Code	Size(mL)	NDC
2B2524	1000	NDC 0338-0168-04

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C); brief exposure up to 40°C does not adversely affect the product.

DIRECTIONS FOR USE OF VIAFLEX PLASTIC CONTAINER
Warning: Do not use plastic containers in series connections. Such use could result in air embolism due to residual air being drawn from the primary container before administration of the fluid from the secondary container is completed.

To Open
Tear overwrap down side at slit and remove solution container. Some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for Administration
1. Suspend container from eyelet support.

2. Remove plastic protector from outlet port at bottom of container.

3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication
Warning: Additives may be incompatible.

To add medication before solution administration
1. Prepare medication site.

2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.

3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration
1. Close clamp on the set.

2. Prepare medication site.

3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.

4. Remove container from IV pole and/or turn to an upright position.

5. Evacuate both ports by squeezing them while container is in the upright position.

6. Mix solution and medication thoroughly.

7. Return container to in use position and continue administration.

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*Bar Code Position Only

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